The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board.

Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SERGEI VINOGRADOV and DAVID F. WILSON

Application No. 08/137,624

ON BRIEF¹

Before WINTERS, SCHEINER, and ADAMS, <u>Administrative Patent Judges</u>.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection. According to appellants "[c]laims 1-7, 14-20, 22-24, 26-45, 47-58 and 59 are pending in this [a]pplication." Brief², § 3, page 2. Claims 8-13, 21, 25, 46 and 60 were canceled. According to appellants "[i]n a Final office Action dated May 9, 1996, claims 1-7, 10 (sic), 14-20, 22-58 and 59 were rejected." Id. After two requests for reconsideration after Final Rejection, the status of the claims remained the same, according to appellants "all of the pending claims 1-7, 14-20, 22-24, 26-

ADAMS, Administrative Patent Judge.

¹ In accordance with 37 CFR 1.194(c), the Board decided that an oral hearing was not necessary in this appeal. Therefore, appellants' request for oral hearing was vacated (Paper No. 28, mailed March 12, 2001).

² Paper No. 18, received February 11, 1997.

45, 47-58 and 59 were rejected." The examiner confirms that "appellant's [sic] statement of the status of amendments after final rejection contained in the brief is correct."

However, upon review of the Answer³ we find no statement of a rejection that refers to claims 38-45, 47-57 and 59. Therefore the rejection of claims 38-45, 47-57 and 59 has been withdrawn, as a matter of standard procedure. Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 663, 231 USPQ 649, 651-652 (Fed. Cir. 1986), cert. denied, 480 U.S. 933 (1987). Accordingly, while we find no statement on this record by the examiner acknowledging this issue, claims 38-45, 47-57 and 59 are free from rejection. In addition, the "INDEX OF CLAIMS" inside the front flap of the File Wrapper fails to reflect that claims 38-45, 47-57 and 59 are free from rejection. Instead, the last entry made in this index was on October 1995, presumably corresponding to the Non-Final Rejection (Paper No. 8) mailed November 6, 1995. As a result, this index fails to correctly identify the status of any claim on appeal.

We further note the examiner's statement (Answer, § 8, page 3) that "[t]he copy of the appealed claims contained in the Appendix to the brief is correct." However, upon review of these claims we note that appealed claim 49 is incorrectly recited, and appealed claim 50 is not recited in appellants' Appendix of claims. As a result, claim 51, as recited in appellants' appendix of claims, is improperly dependent on claim 49.

³ Paper No. 19, mailed June 21, 1997.

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Taken as a whole, we begin our deliberations with something less than a full and complete briefing by the examiner and appellants.

Claims 1, 30 and 59 are illustrative of the subject matter on appeal and are reproduced below:

- 1. A compound for the measurement of oxygen in living tissue comprising a substituted porphyrin which is capable of absorbing an amount of energy and subsequently releasing said energy as phosphorescent light, said substituted porphyrin having an absorption band at a wavelength in the near infra-red region in living tissue and said phosphorescence being quenched by molecular oxygen, said substituted porphyrin being soluble in an aqueous solution.
- 30. A method for preparing a compound of the formula Porph-X-Y-[-CH₂-CH₂-O]_n-H (II) wherein Porph is a porphyrin selected from the group consisting of dihydroporphyrin and metalloporphyrin, X is a chemical bond or a linking group selected from the group consisting of –CO- and –NHCH2CO-, Y is a chemical bond or –O-, and n is an integer from about 8 to about 500, comprising:
 - (a) providing a compound of the formula

 Porph-X-Y-Z

 (III)

where Z is hydrogen, halo or hydroxy; and

- (b) reacting the compound of formula III with PEG at a temperature and for a time to provide a PEG-substituted porphyrin.
- 59. The compound of claim 1 wherein said substituent is a flexible, hydrophilic polymeric compound.

The references relied upon by the examiner are:

Vanderkooi et al. (Vanderkooi)4,947,850Aug. 14, 1990Liu et al. (Liu)5,238,940Aug. 24, 1993Ellis, Jr. et al. (Ellis)5,280,115Jan. 18, 1994Kahl et al. (Kahl)5,284,831Feb. 8, 1994

Robert Thornton Morrison & Robert Neilson Boyd (Morrison), <u>Organic Chemistry</u> 864-865⁴ (5th ed., Allyn and Bacon, Inc. 1987) (1959)

⁴ We note the reference to Morrison in the examiner's "listing of the prior art of record" (Answer, page 3) does not correctly identify all the pages relied upon by the examiner. This error was corrected herein above.

GROUNDS OF REJECTION

- Claims 1-7, 14-20, 22-24 and 58 stand rejected under 35 U.S.C. § 112, first paragraph. According to the examiner, "[t]he terms 'Flexible', [sic] 'hydrophilic', [sic] [and] 'polymeric' in claim 59 leave too much conception to the reader."
- 2. Claims⁵ 1-7, 14-20, 22-24, and 26-29 stand rejected under 35 U.S.C. §102(b) over Vanderkooi.
- Claims 1-7 and 14-20 stand rejected under 35 U.S.C. § 103 as being unpatentable over Vanderkooi as applied to claims 22-24 and 26-59 above⁶, and further in view of Liu.
- 4. Claims 30-37 stand rejected under 35 U.S.C. § 103 as being unpatentable over Morrison.
- 5. Claims 30-37 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kahl in view of Ellis.

We reverse the examiner's rejection of claims 30-37 under 35 U.S.C. § 103 as being unpatentable over Morrison. For reasons which follow, the remaining rejections set forth by the examiner, identified, supra, as rejections 1-3 and 5 are not in condition for a decision on appeal. Therefore, we vacate rejections 1-3 and 5, and remand the application to the examiner to consider the following issues and to take appropriate action.

DISCUSSION

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⁵ We note that canceled claim 10 was incorrectly recited by the examiner in this ground of rejection. This error was corrected herein above.

Rejection #4:

According to the examiner (Answer, page 6):

The instant invention is drawn to a reaction of halogen (as in COCI) with [an] OH group. This is a text book reaction. Morrision and Boyd describes [sic] a reaction of acid chloride and alcohol. The difference is that the instant invention is drawn to porphyrin and glycol derivatives. However, it would have been obvious for one skilled in the art to apply the reaction as taught by the prior art, to porphyrin and PEG derivatives and obtain results similar to the instant invention, because of the similarity of the reacting group.

The claimed process is entirely analogous to and therefore obvious over [the] process in [the] prior art, since the same functional groups react under routine conditions to give a predictable product. It is also obvious that one skilled in the art recognized thionyl chloride and oxalyl chloride are well-known reagents to prepare acid chlorides.

In response appellants argue (Brief, page 18) that:

The Examiner, however, has based his opinion on erroneous and incorrect law. In particular, the Examiner's <u>per se</u> standards that "novel reactants will not alone render the process unobvious" and that "[t]he question of patentability for a process claim is whether the reaction itself is novel and unobvious" are clearly incorrect. On this issue, the Board's attention is respectfully directed to <u>In re Ochiai</u>, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995).

The examiner responds (Answer, pages 9-10) to appellants' argument as

follows:

In re Ochiai [sic] did not overturn any prior case law, certainly not In re Albertson, [sic] 141 USPQ 730. The decision merely says: do not cite case law to me, argue the chemistry. Note how close the prior art is to what is being claimed here, in the manner of Graham vs. John Deere Co., [sic] (USSC 1966), 383 US1 [sic]; 148 USPQ 459 which was done here.

⁶ We note that, in contrast to the examiner's statement of the rejection, we find no rejection of claims 22-24 and 26-59 over Vanderkooi "above."

In Ochiai [sic], the assignee had a patent to the starting materials and to the final product, and were asking for the process of making the final products, that is not the situation here; Chemistry is a teaching of analogous reactions, see Cram & Hammond, 2nd Edition pp. 565-67 (1964). Whether one of ordinary skill in the art would expect the process to proceed as suggested by the prior art is the suggestion provided by the art in the manner of Graham vs. John Deere [sic], above cited.

For a number of reasons we reverse this rejection of claims 30-37. First, the Cram & Hammond reference is not included in a statement of rejection, either in the Final Action⁷ or in the Answer. Where a reference is relied on to support a rejection, whether or not in a "minor capacity," there would appear to be no excuse for not positively including the reference in the statement of the rejection. In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970). Where, as here, the Cram & Hammond reference is not positively included in the statement of rejection under 35 U.S.C. § 103 before us, we shall not consider that reference further. Furthermore we are unable to locate a copy of this reference in the administrative file, or any indication that appellants received a copy of this reference.

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⁷ Paper No. 10, mailed May 9, 1996.

Second, we are unable to identify the portion of <u>In re Ochiai</u>, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) that according to the examiner (Answer, page 9) "merely says: do not cite case law to me, argue the chemistry." In addition, we find no legal precedent to support the examiner's <u>per se</u> conclusion on this record that "[t]he claimed process is entirely analogous to and [is] therefore obvious over [a prior art] process…." Instead, our appellate reviewing court has made it clear that there are no <u>per se</u> rules of obviousness or nonobviousness. <u>In re Ochiai</u>, 71 F.3d at 1572, 37 USPQ2d at 1133 (Fed. Cir. 1995)("reliance on per se rules of obviousness is legally incorrect.") <u>Accord In re Brouwer</u>, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996).

Since there are no <u>per se</u> rules of obviousness or nonobviousness, each case must be decided upon the facts in evidence in that case. <u>See In re Cofer</u>, 354 F.2d 664, 667, 148 USPQ 268, 271 (CCPA 1966)("[n]ecessarily it is facts appearing in the record, rather than prior decisions in and of themselves, which must support the legal conclusion of obviousness under 35 U.S.C. § 103"); and <u>Exparte Goldgaber</u>, 41 USPQ2d 1172, 1176 (Bd. Pat. App. & Int. 1995)("each case under 35 U.S.C. § 103 is decided on its own particular facts").

In evaluating the facts it is well-established that the initial burden of presenting a <u>prima facie</u> case of obviousness under 35 U.S.C. § 103 rests on the examiner. <u>In re Oetiker</u>, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In meeting this burden, it is also well-established that before a conclusion of obviousness may be made, there must be more than the demonstrated existence of all of the components of the claimed subject matter.

There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge cannot come from the applicants' disclosure of the invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988); In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985). On this record we agree with appellants (Reply Brief⁸, page 12) "the Examiner instantly has discussed no references containing any suggestion or motivation to use applicant's [sic] claimed starting materials to obtain the novel water soluble oxygen-quenchable porphyrin compounds recited in the instant claims."

Finally, we note that the examiner makes two references to <u>Graham v. John</u>

<u>Deere Co.</u>, 383 U.S. 1, 148 USPQ 459 (1966) in his response (Answer, pages 9 and 10) to the appellants' arguments. However, in applying a <u>per se</u> rule of obviousness the examiner ignored the principles set forth in <u>Graham v. John Deere</u>

<u>Co.</u> We remind the examiner as set forth in the <u>Manual of Patent</u>

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⁸ Paper No. 22, received November 19, 1997.

Examining Procedure § 706.02(j) (7th ed., Rev. 1, Feb. 2000):

[T]he examiner should set forth in the Office action:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
- (B) the difference or differences in the claim over the applied reference(s),
- (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.

To establish a <u>prima facie</u> case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

On the record before us, we find no suggestion or motivation to modify the teachings of the reference relied upon by the examiner in a manner which would have reasonably led one of ordinary skill in this art to arrive at the claimed invention. Therefore, the examiner failed to provide the evidence necessary to support a <u>prima facie</u> case of obviousness. Where the examiner fails to establish a <u>prima facie</u> case, the rejection is improper and will be overturned. <u>In re Fine</u>, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Accordingly, we reverse the rejection of claims 30-37 under 35 U.S.C. § 103 as being unpatentable over Morrison.

Rejection #1:

Claims 1-7, 14-20, 22-24 and 58 stand rejected under 35 U.S.C. § 112, first paragraph. According to the examiner (Answer, page 4):

The terms "Flexible", [sic] "hybrophilic", [sic] [and] "polymeric" in claim 59 leave too much conception to the reader. After reading the [sic] claim 59, one does not know, what exact structure is intended. A U.S. claim has to be specific. The specification cites only PEG as an example of glycols poly glocols. Thus, the specification is not commensurate with the broad scope of the claims. (Also see arguments in paper #10).

For a number of reasons we are unable to ascertain the basis for the examiner's rejection. First, in explaining this rejection the examiner focuses on the language of claim 59. However, claim 59, which depends from claim 1, is absent from the listing of claims rejected. Therefore, it escapes us how we are to review the merits of this rejection when, according to the examiner's own statement, the claim containing the "offending" limitations is not included in the rejection.

Second, the examiner refers us (Answer, page 4) to the "arguments in paper # 10." Upon review of the examiner's arguments in Paper No. 109 we find (page 2) that the statement of the rejection makes reference to "the reasons cited in paper #8 dated 11/06/95." Upon consideration of Paper No. 8¹⁰ we are referred to Paper No. 6¹¹.

Clearly, the examiner's Answer fails to refer to a single previous Office Action that sets forth an explanation of the examiner's grounds of rejection. In the intervening period between Paper No. 6 and the Answer, claims were canceled and

¹⁰ A Non-Final Rejection, mailed November 6, 1995.

⁹ The Final Rejection, mailed May 9, 1996.

amendments were made. Therefore, it is unclear what the status of the rejection is now, and how the examiner's rejection meets the limitations of the claims presently appearing in the record.

Finally, while we take no position regarding the patentability of the claimed invention it appears that the examiner did not use the correct legal standard to reach the conclusion that the specification is not enabled. The examiner's construction of the rejection suggests to us that the examiner's concern is more of a 35 U.S.C. § 112, second paragraph, claim definiteness/scope issue rather than one of enablement under the first paragraph. One must determine the scope of the claims before one is in a proper position to determine enablement. As set forth in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971), claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art."

However, if the examiner intends a rejection under 35 U.S.C. § 112, first paragraph, it appears that the examiner is questioning whether the disclosure is sufficient to enable the scope of the claimed invention. If this is the case, the examiner failed to evaluate the claimed invention under the proper legal standards. The enablement requirement of 35 U.S.C. or § 112, first paragraph, requires that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation." Genentech, Inc. v.

¹¹ A Final Rejection, mailed May 30, 1995.

Novo Nordisk. A/S, 108 F.3d at 1365, 42 USPQ2d at 1004 (quoting In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)).

Whether making or using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based on several underlying factual inquiries. See In re Wands, 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed. Cir. 1988). As set forth in Wands, the factors to be considered in determining whether a claimed invention is enabled throughout its scope without undue experimentation include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

We find no <u>Wands</u> analysis in this record. Instead, we find only the examiner's unsupported conclusion that the terms presented in "claim 59 leave too much conception to the reader." It is unclear exactly what the examiner intends by this phrase. Nevertheless, in the absence of a fact-based statement of a rejection based upon the relevant legal standards, the examiner has not sustained his initial burden of establishing a <u>prima facie</u> case of non-enablement.

This board functions as a board of review, not a <u>de novo</u> examination tribunal. 35 U.S.C. §7(b)("[t]he Board of Patent Appeals and Interfernces shall ... review adverse decisions of examiners upon application for patents ..."). For the reasons set forth above, the examiner's rejection set forth in the Answer is not susceptible to a meaningful review. Rather than spend the resources of the board in

an attempt to determine what the examiner's position is, we will vacate the rejection and return the application to the examiner for further consideration.

If prosecution is continued, we recommend that the examiner review Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 52 USPQ2d 1129 (Fed. Cir. 1999). Therein, the court provided a model analysis of enablement issues and illustrated the type of fact finding which is needed before one is in a proper position to determine whether a given claim is enabled or non-enabled.

Rejections #2 and #3:

According to the examiner (Answer, page 4) "claims 1-7, 10¹², 14-20, 22-24 and 26-29 are rejected over Vanderkooi ... under 35 U.S.C. [§] 102(b)...." As set forth in RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir 1984) "[a]nticipation is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention" [citation omitted]. We note the examiner's argument (Answer, bridging paragraph, pages 4-5) in support of the rejection under 35 U.S.C. § 102(b) that "Porphyrins (compositions) are phosphorescent ... [and] can be derivatized to esters.... Therefore, the instant esters which are soluble and covalent are clearly anticipated by the prior art." However, in explaining rejection #3, a rejection of claims 1-7 and 14-20 under 35 U.S.C. § 103 over Vanderkooi in view of Lui, the examiner expressly states (Answer, page 5) that Vanderkooi teach that "porphyrings [sic] serve as oxygen

¹² We note that canceled claim 10 is incorrectly recited in this ground of rejection.

quenchable phosphorescent compounds to study oxygen in tissue.... The

differences [sic] is, [the] prior art does not teach soluble porphyrins covalently bound
to hydrophilic substituents" [emphasis added]. While we note that claims 1-7 and
14-20 do not expressly require hydrophilic substituents, these claims do require a
substituted porphyrin ... being soluble in an aqueous solution.

We emphasize that the Vanderkooi reference is relied upon in both the rejection under 35 U.S.C. § 102(b) and the rejection under 35 U.S.C. § 103. However, the examiner's statement of these rejections places the former in conflict with the latter. By rejecting claims 1-7 and 14-20 under both grounds of rejection, and identifying a difference between Vanderkooi and the claimed invention, the examiner has created confusion with respect to his interpretation of the reference and the claimed invention. Stated differently, if there is a difference between Vanderkooi and the claimed invention, how can Vanderkooi anticipate the claimed invention? The possibility exists that the rejections are based on differences in the interpretation of the claim's scope, however, we find no suggestion on this record that the examiner's rejections are based on differences in claim construction.

We further note that, in responding to appellants' arguments the examiner invites our attention to "previous actions" arguing (Answer, page 9) "[t]hat the dye molecules are porphyrins (se [sic] previous actions) is obvious to one skilled in the art." However, the examiner fails to identify any particular "previous action," but instead suggests that the Board engage in a paper chase through the administrative file to ascertain how the examiner would account for the claim

limitation "said substituted porphyrin being soluble in an aqueous solution" in the inconsistent rejections.

We decline the invitation to engage in such a paper chase. Instead, we vacate the examiner's rejection of claims 1-7, 14-20, 22-24 and 26-29 under 35 U.S.C. § 102(b) over Vanderkooi, in addition to the examiner's rejection of claims 1-7 and 14-20 under 35 U.S.C. § 103 over Vanderkooi in view of Lui, and remand this application to the examiner. Upon return of the application, the examiner should take a step back and reevaluate this record together with the relevant prior art. If, on reflection, the examiner finds that a rejection is appropriate, the examiner should issue an appropriate Office action setting forth such rejection, using the proper legal standards and clearly setting for the facts relied upon in support of such a rejection.

We further note that, according to the examiner, "[c]laims 1-7; [sic] [and]14-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Vanderkooi ... as applied to claims 22-24 and 26-59 above, and further in view of Liu...." Aside from including canceled claim 46 in the examiner's reference to claims "26-59," there is no rejection of "claims 22-24 and 26-59" over Vanderkooi "above." The only other rejection on this record that mentions Vanderkooi is a rejection (Answer, page 4) of "claims 1-7, 10, 14-20, 22-24 and 26-29." Again, the examiner incorrectly included canceled claim 10 in that rejection.

Rejection #5:

According to the examiner (Answer, page 7) "[c]laims 30-37 are rejected under 35 U.S.C. § 103 as being unpatentable over Kahl ... in view of Ellis...." We

note appellants' arguments (Brief, page 19-20) against this rejection. Conspicuous by its absence from this record, however, is the examiner's response to appellants' arguments.

As stated in In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986) "[i]f a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed."

Accord In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976)("[w]hen prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over").

We find no indication that the examiner considered appellants' arguments or reweighed the entire merits of the matter in response to appellants' rebuttal. The examiner's list of conclusory statements in the Supplemental Examiner's Answer¹³ also fails to address appellants' original response. Accordingly we vacate the rejection of claims 30-37 under 35 U.S.C. § 103 over Kohl in view of Ellis and we remand the application to the examiner. Upon return of the application, the examiner should take a step back and reevaluate this record in full. If, after a full review of this record and the relevant prior art, the examiner finds that a rejection is appropriate, the examiner should issue an appropriate Office action setting forth such a rejection, using the proper legal standards and clearly setting for the facts relied upon in support of such a rejection.

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¹³ Paper No. 23, mailed February 27, 1998.

This application, by virtue of its "special" status, requires an immediate action. MPEP § 708.01(D) (7th ed., rev. 1, February 2000). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REVERSED-IN-PART; VACATED and REMANDED-IN-PART

Sherman D. Winters) Administrative Patent Judge)
))) BOARD OF PATENT
Toni R. Scheiner Administrative Patent Judge) APPEALS AND
)) INTERFERENCES)
Donald E. Adams Administrative Patent Judge))

DA/dym

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